

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0189070	(X3) Date Survey Completed 10/24/2023
Name of Provider or Supplier Bucktail Medical Center	Street Address, City, State 1001 Pine Street, South Renovo, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5213	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to verify the accuracy of analytes that were not evaluated or scored for 2 of 3 WSLH hematology/coagulation PT events in 2023. Findings include: 1. On the day of survey, 10/24/2023 at 12:15 PM, review of the laboratory's WSLH PT records revealed that the laboratory did not verify the accuracy for the following WSLH PT events that were not graded due to non consensus in 2021,2022, and 2023: WSLH PT 2023 HemeReg1- Toxic Granulation- Basophil WSLH PT 2023 SpecialChemistry2-Tumor Markers Prostate Specific Antigen (PSA) WSLH PT 2023 Chem/Endo/TX1- Chemistry CO2 WSLH PT 2022 SpecialChemistry2- Tumor Markers Prostate Specific Antigen (PSA) WSLH PT 2022 BloodGas1- Chemistry Urea Nitrogen (BUN) WSLH PT 2022 BloodGas2- Chemistry Urea Nitrogen (BUN) WSLH PT 2022 Chem/Endo/Tx1- Chemistry Alanine Aminotransferase (ALT) WSLH PT 2021 Chem/Endo/Tx3- Chemistry Cholesterol WSLH PT 2021 Chem/Endo/Tx3- Chemistry Lipase WSLH PT 2021 HemeReg3-Hematology RDW WSLH PT 2021 BloodGas3- Chemistry Urea Nitrogen (BUN) 2. The TS confirmed the findings above on 10/24/2023 at 04:00 PM.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or</p>

instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with the Technical Supervisor (TS), the laboratory failed to have a system that twice a year evaluates and defines the relationship between test results using different methodologies and instrumentation for examinations performed in hematology from 10/13/2021 to the date of the survey. Findings include: 1. On the day of the survey, 10/24/2023, the laboratory failed to provide documentation of the biannual comparison of test results for the following tests performed in hematology from 10/13/2021 to 10/24/2023: -White blood cell differentials: manual microscopic vs. automated (Sysmex XNL 430) 2. The laboratory performed 14,460 hematology tests in 2022 (CMS 116 annual volume). 3. The TS confirmed the findings above on 10/23/2023 at 04:10 PM.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of competency assessment records and interview with the Technical Supervisor (TS), the TS failed to assess the competency of 13 of 16 testing personnel (TP) that performed Clinical Chemistry, Virology and Urinalysis testing in 2022. Findings include: 1. On the day of the survey, 10/26/2023, at 10:11 AM, review of the laboratory's competency assessment records and patient test reports revealed that the TS did not assess the competency of 13 of the TP (CMS 209 TP #2, 3,4,5,6,7,8,9,10,11,12,13,14) that performed Clinical Chemistry, Virology and Urinalysis testing in 2022. 2. The TS confirmed the findings above on 10/26/2023 at 04:00 PM.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Individualized Quality Control Plan (IQCP) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to maintain a quality assessment program to assure the quality of laboratory services provided in microbiology and coagulation testing performed in 2022 and 2023. Findings Included: 1. On the day of survey, 10/24/2023 at 3:30 PM, a review of laboratory's IQCP record revealed that the LD failed to review the IQCP for the following tests performed in 2022 and 2023. - D Dimer. - Clostridium difficile (C

diff). 2. According to the laboratory's IQCP procedure, the LD should review the IQCP procedure yearly. 3. The TS confirmed the findings above on 10/24/2023 at 4:00 PM.